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November 2, 2016

VIA ELECTRONIC COURT FILING

The Honorable Gary L. Sharpe, Chief Judge
U.S. District Court, Northern District of New York
James T. Foley - U.S. Courthouse
445 Broadway
Albany, NY 12207

Re: *Alleyne, et al. v. New York State Education Department, et al.*; N.D.N.Y. No. 1:06-CV-994 (GLS)

Dear Judge Sharpe:

Please accept this letter as Plaintiffs' status report on the progress of the Judge Rotenberg Educational Center, Inc.'s ("JRC") 510(k) application, filed pursuant to the Court's recent Order, dated April 11, 2016 (the "Court Order"). As previously reported to the Court, on January 9, 2013 the U.S. Food and Drug Administration ("FDA") asked JRC to file with the FDA a pre-510(k) submission, which JRC did on February 1, 2013. After JRC filed the pre-510(k), the FDA requested that JRC give the FDA an opportunity to review the pre-510(k) submission before JRC files the 510(k) application. The FDA has not responded to JRC's pre-510(k) submission.

On April 1, 2014, JRC was informed by the FDA "that The Center for Devices and Radiological Health (CDRH), Neurological Devices Panel of the Medical Devices Advisory Committee of the Food and Drug Administration, will be holding an advisory committee meeting for Thursday, April 24, 2014 at Holiday Inn, Main Ballroom, 2 Montgomery Village Ave in Gaithersburg, MD to discuss the current knowledge about the safety and effectiveness of aversive conditioning devices. The Agency is considering whether to ban aversive conditioning devices that are intended to administer a noxious electrical stimulus to a patient to modify undesirable behavioral characteristics." The FDA's "Summary of the Neurological Devices Panel Meeting" is posted at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM395022.pdf. JRC expected to hear next from the FDA after close of the public comment period, which was on June 24, 2014. On April 22, 2016, the FDA announced a proposal to ban electrical stimulation devices intended to treat self-injurious or aggressive behavior. The FDA's proposed rule is posted at https://www.federalregister.gov/articles/2016/04/25/2016-09433/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or. The proposed rule was subject to a public comment period, which ran

through July 25, 2016. The FDA's proposed rule states that "[t]he purpose of this proposed rule is to seek comments on these determinations as well as seek comments on FDA's proposal to ban ESDs used for SIB or AB and comments on any other associated issues." At this time, it is unclear whether the proposed rule will be approved and/or in what form. We will continue to keep the Court apprised pursuant to the May 29, 2013 and April 11, 2016 Court Orders.

If you need anything further, then please contact me. Thank you.

Very truly yours,

/s/ Michael P. Flammia
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cc: Jeffery J. Sherrin, Esq. (by electronic court filing)
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